



Pub. 605

FORM 6-3

6-41

Practitioner's Docket No. 2605/101

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

**OR**

In re application of: Miyata et al.

Application No : 10/018,311  
Filed: October 30, 2001  
For: Meg-3 protein

Group Art Unit: N/A  
Examiner: N/A

**Commissioner for Patents  
Washington, D.C. 20231**

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN  
THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))**

*NOTE:* "An information disclosure statement shall be considered by the Office if filed by the applicant. (1) within three months of the filing date of a national application; (1) within three months of the date of entry of the national stage as set forth in § 1.491 in an International application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. § 1.97(b)

**CERTIFICATE of MAILING/TRANSMISSION (37 C.F.R. § 1.8(a))**

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

☒ deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

Date: February 7, 2002

**FACSIMILE**

☐ transmitted by facsimile to the Patent and Trademark Office.

\_\_\_\_\_  
Signature

Harriet M. Strimpel, D.Phil.  
(type or print name of person certifying)

**NOTE.** The "filing date of a national application" under 37 C.F.R. § 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. § 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. § 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. § 1.97(b)(2).

### IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

**NOTE:** "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

**NOTE:** "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "The term national application" includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**NOTE:** "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosures statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

Reg. No.: 644658

\_\_\_\_\_  
Signature of Practitioner

Tel. No.: 617/443-9292

\_\_\_\_\_  
Harriet M. Strimpel, D.Phil.  
(type or print name of practitioner)

Customer No.: 00-2101

Bromberg & Sunstein LLP  
125 Summer Street, Boston, MA 02110



Practitioner's Docket No. 2605/101

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

**OR**

In re application of: Miyata et al.

Application No.: 10/018,311  
Filed: October 30, 2001  
For: Meg-3 protein

Group Art Unit: N/A  
Examiner: N/A

**Commissioner for Patents  
Washington, D.C. 20231**

**INFORMATION DISCLOSURE STATEMENT**

**CERTIFICATE UNDER 37 C.F.R. § 1.8(a) and 1.10\***  
(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231

**37 C.F.R. § 1.8(a)**

**37 C.F.R. § 1.10\***

- ☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

Mailing Label No. \_\_\_\_\_ (**mandatory**)

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: February 7, 2002

Signature \_\_\_\_\_

Harriet M. Strimpel, D.Phil.  
(type or print name of person certifying)

(Information Disclosure Statement [6-1]--page 1 of 6)



NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) Before the mailing date of a first Office action on the merits; or
- (4) Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O. G. 13 -25 at 17.

**WARNING:** "No information disclosure statement maybe filed in a provisional application." 37 C.F.R. § 1.51(d).

### List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

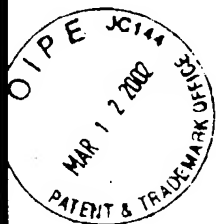
(check sections forming a part of this statement; discard unused sections and number pages consecutively)

- 1 ☒ Preliminary Statements
- 2 ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
- 3 ☐ Statement as to Information Not Found in Patents or Publications
- 4 ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
- 5 ☐ Cumulative Patents or Publications
- 6 ☒ Copies of Listed Information Items Accompanying This Statement
- 7 ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. EPO Search Report
  - 7B. English Language Version of EPO Search Report
- 8 ☐ Translation(s) of Non-English Language Documents
- 9 ☐ Concise Explanation of English Language Listed Information Items (Optional)
- 10 ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S) \_\_\_\_\_.

NOTE: "Once the minimum requirements are met the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).



## Section 1. Preliminary Statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



**Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Miyata et al. Attorney Docket: 2605/101  
 Serial No: 10.018.311 Art Group Unit: N/A  
 Date Filed: October 30, 2001 Examiner Name: Not Assigned  
 Invention: Meg-3 protein

**LIST OF PATENTS AND PUBLICATIONS FOR  
 APPLICANT'S INFORMATION DISCLOSURE STATEMENT**

**International Patents**

Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
<u>EPA</u>	AA	EP 0780472 A2	25.06.1997	Ikeda et al.	C12N 15/12
<u>EPA</u>	AB	WO99/33981	08.07.1999	Lal et al.	C12N 15/12

**Other Documents**

Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
<u>EPA</u>	AC	Yasuda et al.	Functional Quantitative Analysis of the Genome in Cultured Human Mesangial Cells. Kidney Int., Vol. 53, No. 1, pages 154-158, 1998
<u>EPA</u>	AD	Miyata et al.	A Mesangium-predominant Gene, Megsin, Is a New Serpin Upregulated in IgA Nephropathy. J. Clin. Invest., Vol. 120, No. 4, pages 828-836, 1998
<u>EPA</u>	AE	Terada et al.	Gendai Iryo, Vol. 32, No. 3, pages 745-750, 2000

Examiner Signature: Eileen B. O'Hara  
 Date Considered: 1/27/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

02605 00101 189840.1



## Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. § 198(a)(2) requires that any information disclosure statement filed under § 1.97 shall include:

"A legible copy of:

- (i) Each U.S. patent application publication and U.S. and foreign patent;
- (ii) Each publication or that portion which caused it to be listed,
- (iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion. . .

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

Exception(s) to above:

- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.



### Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
(type or print name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
(type or print name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
- ☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
- ☒ in the practitioner's file.

Reg. No.: 644658

\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

Tel. No.: 617/443-9292

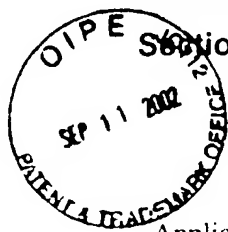
\_\_\_\_\_  
Harriet M. Strimpel, D.Phil.  
(type or print name of practitioner)

Customer No.: 00-2101

Bromberg & Sunstein LLP  
125 Summer Street, Boston, MA 02110

(Information Disclosure Statement-Section 10. Identification of Person(s) Making This Information Disclosure Statement [6-1]-page 6 of 6)





## Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Miyata et al. Attorney Docket: 2605/101  
 Serial No: 10/018,311 Art Group Unit: Not yet assigned  
 Date Filed: October 30, 2001 Examiner Name: Not yet assigned  
 Invention: **MEG-3 PROTEIN**

TECH CENTER 1600/2900

SEP 16 2004

RECEIVED

### LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

#### International Applications

Examiner Initials	Ref. No.	Document Number	Filed	Inventor	Class/Subclass
<u>EJA</u>	AF	WO98/54963 (in English)	6/4/98	Young et al.	A01N 37/18
<u>EJA</u>	AG	WO99/47655 (in German). Attached to the German language Publication is an English language abstract of the invention that was obtained from from the British Mirror web site of the EPO's ESpace-net web site. This abstract appears to be more detailed than that of the German language PCT Publication WO99/47655 itself.	3/19/99	Specht et al.	C12N 15/00

Examiner Signature: Eileen B. O'Hara

Date Considered: 1/27/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

## Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. § 198(a)(2) requires that any information disclosure statement filed under § 1.97 shall include:

"A legible copy of:.

- (i) Each U.S. patent application publication and U.S. and foreign patent;
- (ii) Each publication or that portion which caused it to be listed,
- (iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion. . .

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

Exception(s) to above:

- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.



**Section 7A. Concise Explanation of Non-English Language Listed  
Information Items-EPO Search Report**

The relevance with respect to the following citations listed on Forms PTO/SB/08A and 08B (formerly Form PTO-1449):



is submitted on the basis of the accompanying:

*(check the appropriate item)*

- ☒ EPO search report that is in the English language,
- ☐ EPO search report that is not in the English language and that is accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
(type or print name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
(type or print name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
- ☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
- ☒ in the practitioner's file.

Reg. No.: 34465

Tel. No.: 617/443-9292

Customer No.: 00-2101

\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

Morton Chirnomas  
(type or print name of practitioner)

Bromberg & Sunstein LLP  
125 Summer Street, Boston, MA 02110



RECEIVED

SEP 16 2002

CENTER 1600 2900

(Ref. 77-10 98 Pub. 605)

FORM 6-3

6-41



Practitioner's Docket No. 2605/101

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_

Inventor(s)

for \_\_\_\_\_

Title of invention

**OR**

In re application of: Miyata et al.

Application No.: 10/018,311

Group Art Unit: N/A

Filed: October 30, 2001

Examiner: N/A

For: Meg-3 protein

**Commissioner for Patents  
Washington, D.C. 20231**

**TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))**

*NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant, (1) within three months of the filing date of a national application; (1) within three months of the date of entry of the national stage as set forth in § 1.491 in an International application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. § 1.97(b)*

**CERTIFICATE UNDER 37 C.F.R. § 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

- ☐ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231

**37 C.F.R. § 1.8(a)**

**37 C.F.R. § 1.10\***

- ☐ with sufficient postage as first class mail.

☒ as "Express Mail Post Office to Addressee"  
Mailing Label No. EL289073775US

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: September 11, 2002

Signature

Morton Chirnomas

(Type or print name of person certifying)

RECEIVED

SEP 16 2002

TECHNICAL CENTER 1000 2900

(Rel. 7-10-98 Pub.605)

FORM 6-3

6-42

NOTE: The "filing date of a national application" under 37 C.F.R. § 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. § 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. § 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. § 1.97(b)(2).



### IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term national application" includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosures statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

Reg. No.: 34465

Tel. No.: 617/443-9292

Customer No.: 00-2101

Signature of Practitioner

Morton Chirnomas.

(type or print name of practitioner)

Bromberg & Sunstein LLP  
125 Summer Street, Boston, MA 02110

Practitioner's Docket No. 2605/101**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_

Inventor(s)

for \_\_\_\_\_

Title of invention

**OR**

In re application of: Miyata et al.

Application No.: 10/018,311

Filed: October 30, 2001

For: Meg-3 protein

Group Art Unit: N/A

Examiner: N/A

**Commissioner for Patents  
Washington, D.C. 20231****SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT****CERTIFICATE UNDER 37 C.F.R. § 1.8(a) and 1.10\****(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

- ☐ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231

**37 C.F.R. § 1.8(a)****37 C.F.R. § 1.10\***

- ☐ with sufficient postage as first class mail.

- ☒ as "Express Mail Post Office to Addressee"  
Mailing Label No. EL289073775US

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: September 11, 2002

Signature

Morton Chirnomas

(type or print name of person certifying)

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:



- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) Before the mailing date of a first Office action on the merits; or
- (4) Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O. G. 13-25 at 17.

**WARNING:** "No information disclosure statement maybe filed in a provisional application." 37 C.F.R. § 1.51(d).

### List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☒ Concise Explanation of Non-English Language Listed Information Items
  - 7A. EPO Search Report
  - 7B. English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).



**Section 1. Preliminary Statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**Section 2. Forms PTO/SB/08A and 08B (formerly Form PTO-1449)****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Miyata et al. Attorney Docket: 2605/101  
Serial No: 10/018,311 Art Group Unit: Not yet assigned  
Date Filed: October 30, 2001 Examiner Name: Not yet assigned  
Invention: MEG-3 PROTEIN

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE STATEMENT****Other Documents**

Examiner Initials	Ref. No.	Title of Article, Title of Item, Date, Pages
<u>EA</u>	AH	DATABASE EMBL 'Online! 15 June 1998 (1998-06-15) ZHANG WP ET AL.: "BE0002 monocyte-derived dendritic cell library Homo sapiens cDNA HDA003 5', mSRNA sequence" retrieved from EMBL Database Accession No. AI003761 XP002200765 *abstract*

Examiner Signature: Cileen B. O'HaraDate Considered: 1/27/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.



## Section 6. Copies of Listed Information Items Accompanying This Statement

*NOTE: 37 C.F.R. § 198(a)(2) requires that any information disclosure statement filed under § 1.97 shall include:*

*"A legible copy of.:*

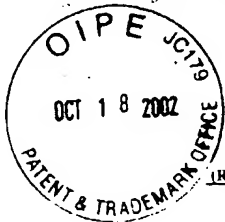
- (i) Each U.S. patent application publication and U.S. and foreign patent;*
- (ii) Each publication or that portion which caused it to be listed,*
- (iii) For each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion. . .*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

Exception(s) to above:

- ☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- ☐ Cumulative patents or publications identified in Section 5.



(Rel. 85-11/00 Pub.605)

FORM 6-1

6-32

### Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this statement is

(check each applicable item)

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
(type or print name of inventor who is signing)

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

\_\_\_\_\_  
SIGNATURE OF INVENTOR

\_\_\_\_\_  
(type or print name of inventor who is signing)

- (c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

- ☐ supplied by the inventor(s).
- ☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))
- ☒ in the practitioner's file.

Reg. No.: 34465

Tel. No.: 617/443-9292

Customer No.: 00-2101

\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

Morton Chirnomas  
(type or print name of practitioner)

Bromberg & Sunstein LLP  
125 Summer Street, Boston, MA 02110

(Information Disclosure Statement-Section 10. Identification of Person(s) Making This Information Disclosure Statement [6-1]-page 6 of 6)

02605/00101 222863 1



MC/nsj

PLEASE DATE STAMP AND RETURN  
The Commissioner for Patents has received from Bromberg & Suscille LLP the following re:

Inventor: Miyata et al.

Docket No. 2605/101

Title: Meg-3 protein

Art Unit: N/A

Serial/Parent No. 10/018,311

Examiner: N/A

Filing/Laure Date: October 30, 2001

Date: 10/18/02

Documents:

Express Mail No. EL289073660US

( ) New Application Transmittal

( ) Amendment Transmittal

( ) Provisional Application Cover Sheet

( ) Amendment (Preliminary)

( ) Description - \_\_\_\_\_ pages

( ) Response \_\_\_\_\_

( ) Claims - \_\_\_\_\_ pages

( ) IDS & References - AH -

( ) Abstract

( ) Petition for \_\_\_\_\_ month Extension

( ) \_\_\_\_\_ sheets of drawings

( ) Transmittal of Formal Drawings

( ) Declaration & Power of Attorney

( ) Issue Fee Transmittal & Form PTO-L-45b

( ) executed ( ) unexecuted

( ) Payment of \_\_\_\_\_ Maintenance Fee

( ) Small Entity Statement

( ) Check in the amount of \$ \_\_\_\_\_

( ) Assignment/Recordation Form Cover Sheet

( ) Completion of Filing Requirements

( ) Request for Corrected Filing Receipt



10:21:02

DT06 Rec'd PCT

18 OCT 2002

PCT

Pat. 77-10/98 Pub. 605)

FORM 6-3

6-41

Practitioner's Docket No. 2605/101

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

**OR**

In re application of: Miyata et al.

Application No.: 10/018,311

Filed: October 30, 2001

For: Meg-3 protein

Group Art Unit: N/A

Examiner: N/A

**Commissioner for Patents  
Washington, D.C. 20231**

**TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))**

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant. (1) within three months of the filing date of a national application; (1) within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. § 1.97(b)

**CERTIFICATE UNDER 37 C.F.R. § 1.8(a) and 1.10\***

(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231

**37 C.F.R. § 1.8(a)**

**37 C.F.R. § 1.10\***

- ☐ with sufficient postage as first class mail.

- ☒ as "Express Mail Post Office to Addressee"

Mailing Label No **EL289073660US**

**TRANSMISSION**

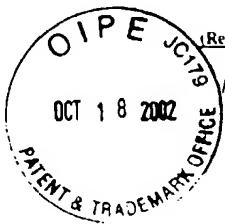
- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: October 18, 2002

Signature

Morton Chirnomas

(type or print name of person certifying)



NOTE: The "filing date of a national application" under 37 C.F.R. § 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. § 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. § 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. § 1.97(b)(2).

### IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosures statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

Reg. No.: 34465

  
Signature of Practitioner

Tel. No.: 617/443-9292

Morton Chirnomas.  
(type or print name of practitioner)

Customer No.: 00-2101

Bromberg & Sunstein LLP  
125 Summer Street, Boston, MA 02110



EL 85-11/00 Pub.605)

FORM 6-1

6-17

Practitioner's Docket No. 2605/101

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_  
Inventor(s)

for \_\_\_\_\_  
Title of invention

**OR**

In re application of: Miyata et al.

Application No.: 10/018,311

Filed: October 30, 2001

For: Meg-3 protein

Group Art Unit: N/A

Examiner: N/A

**Commissioner for Patents  
Washington, D.C. 20231**

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

**CERTIFICATE UNDER 37 C.F.R. § 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)*

I hereby certify that this correspondence is, on the date shown below, being:

**MAILING**

- ☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231

**37 C.F.R. § 1.8(a)**

**37 C.F.R. § 1.10\***


- ☐ with sufficient postage as first class mail.

- ☒ as "Express Mail Post Office to Addressee"  
Mailing Label No. EL289073 **US**  
**660**

**TRANSMISSION**

- ☐ transmitted by facsimile to the Patent and Trademark Office.

Date: October 18, 2002

  
Signature

Morton Chirnomas  
(type or print name of person certifying)





NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant within any one of the following time periods:

- (1) Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- (2) Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- (3) Before the mailing date of a first Office action on the merits; or
- (4) Before the mailing date of a first Office action after the filing of a request for continued examination under § 1.114."

37 C.F.R. § 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. § 1.56(c).

NOTE: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O. G. 13 -25 at 17.

**WARNING:** "No information disclosure statement maybe filed in a provisional application." 37 C.F.R. § 1.51(d).

### List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:  
(check sections forming a part of this statement: discard *unused* sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ FORMS PTO/SB/08A and 08B (formerly FORM PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - ☒ 7A. EPO Search Report
  - ☐ 7B. English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

NOTE: "Once the minimum requirements are met the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).



### **Section 1. Preliminary Statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. § 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.